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JUN 13 2005

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention; Claudia Grillo

Dear Ms. Axelrad:

The attached application for patent term extension of U.S. Patent No. 6,001,876 was filed on February 25, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Lyrica™ (pregabalin), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156, based upon the approval of NDA No. 21-723 on December 30, 2004. An application for patent term extension was also filed for U.S. Patent No. 6,197,819, based upon the regulatory review period of NDA No. 21-446. Because the two NDAs were approved on the same day, both patents appear eligible for extension.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7744 (telephone) or (571)273-7744 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Karen DeBenedictis
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